K020112

APR 19 2002

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Densmore, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
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Contact Person: Colleen Densmore

Date: December 20, 2001

807.92(a)(2)

Trade Name:	50S Tringa Ultrasound Imaging System	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed echo imaging system	892.1560
Classification Number:	90IYO	

807.92(a)(3)

Predicate Device(s)

Pie Medical	100S	K002357
Esaote	7200 (Caris)	K981293

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

RA 11

SK 141

510(k) Summary
50S Tringa
Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 50S Tringa ultrasound system is used by or under the direction of a physician to perform general non-invasive diagnostic ultrasound imaging studies, to include: abdominal, peripheral vascular, fetal, small organ & cardiac applications.

Comparison Chart for Substantial Equivalence

General characteristics	Pie Medical 50S Tringa This submission	Pie Medical Scanner 100S K002357	Esaote 7200 (Caris) K981293
Intended use			
Fetal	Yes	Yes	Yes
Abdominal	Yes	Yes	Yes
Pediatric	Yes	Yes	Yes
Small Organ	Yes	Yes	Yes
Neonatal Cephalic	No	Yes	Yes
Adult Cephalic	No	No	Yes
Cardiac	Yes	Yes	Yes
Transesophageal	No	No	Yes
Transrectal	No	Yes	No
Transvaginal	No	Yes	No
Transurethral	No	No	No
Intravascular	No	No	No
Peripheral Vascular	Yes	Yes	Yes
Musculoskeletal	No	No	No
Transducer type			
Annular Array	Yes	Yes	Yes
Linear	No	No	No
Convex	No	No	No
2D Freq MHz	3.5/5.0/7.5	3.5/5.0/7.5	2.5/3.5/5.0/7.5/10
CFM/Doppler Freq MHz	N/A	N/A	2.0/2.5/3.3/5.0/6.6
Biopsy Guidance	No	Yes	No
Display type	LCD	B/W	SVGA and LCD
Imaging modes	2D / M-Mode	2D / M-Mode	2D / M-Mode / PW / CW / CFM
Monitor size (inches)	5.4	9	15 (SVGA) and 10 (LCD)
Digital archival capabilities	Yes	Yes	Yes
VCR	Yes	Yes	Yes
M&A capabilities	Cardiac, Fetal, Abdominal	Cardiac,Fetal, Obstetrics , Abdominal Urology	Cardiac, Vascular, Fetal, Abdominal
Safety			
Electrical safety	EN60601-1	EN60601-1	EN60601-1
Ultrasound safety	Track 1	Track 1	Track 3

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2002

Pie Medical
% Ms. Colleen J. Densmore
Official Correspondent
The Anson Group, LLC
7992 Castleway Drive
INDIANAPOLIS IN 46250

Re: K020112
Trade Name: 50S Tringa Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO, and 90 ITX
Dated: March 26, 2002
Received: March 27, 2002

Dear Ms. Densmore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 50S Tringa Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

3.5/5.0 MHz Mechanical Probe
5.0/7.5 MHz Mechanical Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

50S Tringa

50S Tringa (410697)

	Mode of Operation								
Clinical application	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N					N	
Abdominal		N	N					N	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)		N	N					N	
Neonatal Cephalic									
Adult Cephalic									
Cardiac		N	N					N	
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N					N	
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication

Combined is: B+B mode and B+M mode

Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020112

Diagnostic Ultrasound Indications for Use Form

50S Tringa

3.5/5.0 MHz Mechanical probe (410047)

Clinical application	Mode of Operation								
	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N					N	
Abdominal		N	N					N	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)		N	N					N	
Neonatal Cephalic									
Adult Cephalic									
Cardiac		N	N					N	
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N					N	
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
Combined is: B+B mode and B+M mode

Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K020112

Diagnostic Ultrasound Indications for Use Form

50S Tringa

5.0/7.5 MHz Mechanical probe (410048)

	Mode of Operation								
Clinical application	A	B	M	PWD (D)	Color Doppler (CD)	Amplitude Doppler (AD)	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic									
Fetal		N	N					N	
Abdominal		N	N					N	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)		N	N					N	
Neonatal Cephalic									
Adult Cephalic									
Cardiac		N	N					N	
Transesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N					N	
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

N=new indication
Combined is: B+B mode and B+M mode

Additional comments:
* Small organs include Thyroid, Breast and Testicles

Prescription Use ✓
(Per 21 CFR 801.109)

Nancy C Brogdon
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